

## REMARKS

The Official Action of November 29<sup>th</sup> 2007 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claims 28 and 74 have been amended to remove the term “significantly” and to make it clear that an improvement in physical work capacity in a subject occurs with no detectable change in plasma IGF-I concentrations. This is supported by the specification on page 28, line 16 – 18. These amendments have necessitated further amendments in claim 37, 39, 47 and 75.

Applicants preserve all rights to file one or more divisional applications for any subject matter disclosed in this application and not presently claimed.

### **35 U.S.C. 112**

The Examiner submits that claims 28-39, 46-48 and 74-75 are rejected on the basis they are indefinite. In response the term “significantly” has been removed from the claims.

### **35 U.S.C. 103(a)**

The claims are rejected under 35 USC 103(a) as allegedly being unpatentable over

WO 97/16977. AU-A-63136/94. Clark et al. and Ballard et al. (US patent 6,319,522).

Applicant respectfully traverses this rejection.

The present invention is directed to a method of improving the physical work capacity of a subject as opposed to treating infectious diseases with the use of antibodies. The improvement in physical work capacity occurs without a detectable change in plasma IGF-1 concentrations and the method comprises ingesting a colostrum fraction which is prepared by subjecting colostrum to ultrafiltration to provide a specific retentate fraction including colostrum derived growth factors and casein and subsequently spray drying the retentate fraction. The invention is based at least in part upon Applicants finding that the claimed retentate fraction preserves a combination of components when ingested and hence can improve the physical work capacity of the subject.

Contrary to the present invention, the cited art does not show or suggest the specific retentate fraction as claimed. WO97/16977 relates to processing colostrum to maintain colostrum antibodies which is used to treat infectious conditions. Similarly, AU-A-63136/94 relates to a process which preserves proteins such as antibodies in the colostrum and discloses a colostrum preparation to improve antibody content so as to provide antibody enriched colostrum to treat infectious diseases. Finally Ballard et al. merely discloses reconstituting freeze dried powder of colostrum. None of these references provides any motivation or reasoning for isolating the claimed retentate fraction from colostrum.

The Examiner submits that Clark et al. teach that colostrum contains IGF-1 and that

maintaining IGF-1 levels and proper nutritional intake is required if a person is to expect to achieve weight reduction and improved body condition. However Applicants submit that this is not a teaching of the claimed retentate fraction. It is also not a teaching of improving the physical work capacity without a detectable change in plasma IGF-1 concentrations of a subject by ingesting a colostrum fraction. This is supported by the fact that the Affidavit shows that the improvement in physical work capacity is not due to an increase in circulating IGF-1 levels (see point 9).

In the absence of any motivation or reason in the prior art for isolating and ingesting the claimed retentate fraction the references respectfully do not set forth even a prima facie case of obviousness for the invention as claimed.

The Examiner nevertheless submits that Clark et al. teach that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue. The Examiner contends that improved exercise performance is noted in that it is disclosed that physical stress from exercise causes fatigue, infection etc. and that colostrum reduces these symptoms and points to column 44, second paragraph, lines 6-10. However Applicants submit that, contrary to the Examiner's contention, Clark et al. at column 44, second paragraph, lines 6-10 actually teach that colostrum's many immune factors demonstrate a significant reduction in the occurrence and severity of numerous types of infections caused by physical and emotional stress and this provides no indication of improved exercise performance.

The Examiner also submits that Clark et al. teach that the effectiveness of colostrum

depends upon how it is produced or processed. Applicants submit that there are many ways of processing colostrum and the claims are directed to one particular way that provides a specific fraction of colostrum which has the effect of improving physical work capacity. Clark et al provide no teaching of any specific method that provides the claimed fraction or any specific colostrum fraction which improves physical work capacity.

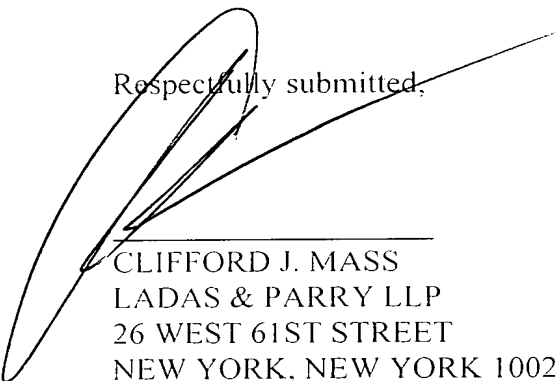
Finally the Examiner argues that there is no unexpected result obtained by present invention and that a colostrum having IGF-1 clearly would have provided successful results. In response Applicants submit it is indeed surprising that the specific colostrum fraction according to the present invention improves the physical work capacity without showing an increase in circulating IGF-1 levels and therefore unexpected results have been clearly illustrated.

In short, Applicants submit that there is no teaching in either WO97/16977, AU-A-63136/94 or Ballard et al. of producing a retentate fraction according to that prepared by the present invention that is capable of being ingested and improving the physical work capacity of a subject. Furthermore Clark et al do not provide any teaching of a method of processing colostrum to provide a colostrum fraction that can improve physical work capacity and no disclosure that even whole colostrum can improve physical work capacity.

Applicants therefore submit that the cited art does not disclose or suggest the above mentioned features and that therefore there can be no articulated reasoning with rational underpinning to support a legal conclusion of obviousness (see MPEP 2142).

In view of the foregoing, it is respectfully submitted that all rejections and objections of record have been overcome and that this application is now in order for allowance. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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